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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,936	11/17/1999	GUST H. BARDY	90980054-1	5202

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
P.O. BOX 3001
BRIARCLIFF MANOR, NY 10510

EXAMINER	
DROESCH, KRISTEN L	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 12/31/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/441,936	BARDY ET AL.	
	Examiner	Art Unit	
	Kristen L Droesch	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/19/03 (Decision)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-12,16,17 and 20-23* is/are allowed.

6)☒ Claim(s) *13,14,18 and 19* is/are rejected.

7)☒ Claim(s) *15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. In view of the Decision of Appeal mailed on Nov. 19, 2003, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 13, and 18-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Druz (3,442,269). Druz shows a method of receiving a cardiac signal from a patient (Col. 3, line 56-Col. 4, line 9, Col. 6, lines 17-22); receiving a shock command from an operator (Col. 7, lines 1-12) and shocking the patient with a portable shock generator (Col. 2, lines 63-64) in response to the shock command if the patient is experiencing atrial fibrillation. Although Druz fails to specifically show the step of determining

from the signal whether the patient is experiencing atrial fibrillation, Druz shows it is desirable to monitor the patient's heart before and after defibrillation (Col. 2. lines 1-11). It is inherent that the step of determining from the signal whether the patient is experiencing atrial fibrillation is performed by a doctor or similar well-trained medical person who is monitoring the patient's heart beat before defibrillation. See Spivak (3,453,745) who shows a device utilized to train physicians to recognize various arrhythmias on the display including atrial fibrillation and apply defibrillating energy as needed.

In the alternative, it would have been obvious to one with ordinary skill in the art at the time the invention was made to perform the step of determining from the signal whether the patient is experiencing atrial fibrillation since it is an essential step in the application of a shock for treatment of atrial fibrillation and it would be dangerous and unnecessary to apply a shock otherwise.

Regarding claim 18, although Druz fails to specifically show determining from the cardiac signal whether the atrial fibrillation terminates after shocking the patient, Druz shows it is desirable to monitor the patient's heart before and after defibrillation (Col. 2. lines 1-11). It is inherent that the step of determining from the cardiac signal whether the atrial fibrillation terminates after shocking the patient is performed by a doctor or similar well-trained medical personnel who is monitoring the patient's heart beat after defibrillation.

In the alternative, it would have been obvious to one with ordinary skill in the art at the time the invention was made to perform the step of determining from the signal whether the atrial fibrillation terminates after shocking the patient, since it is necessary step in the evaluation of the patient and the determination of whether additional shocks may be needed. Furthermore,

it would be negligent of a doctor or similar well trained medical person to not make this determination following the application of an atrial defibrillation shock.

With respect to claim 19, Druz shows shocking the patient during a rising edge of an R wave during the cardiac signal (Col. 6, lines 32-62)

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Druz in view of Ferrari (5,824,033). Druz shows applying defibrillator pads to the patient (Col. 5, lines 53-57) and shocking the patient via the pads. Although Druz fails to show receiving the cardiac signal via the defibrillator pads but shows receiving the cardiac electric signal by separate electrodes (Col. 6, lines 17-22), attention is directed to Ferrari who shows defibrillator pads that are also used for receiving cardiac electrical signals (Col. 8, lines 51). It would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize defibrillation pads capable of receiving cardiac electrical signals as Ferarri teaches in the method of Druz, since it is well known in the art to utilize combination defibrillator/ECG pads as a means for limiting the number of electrodes applied to the patient and the number of connections to the external defibrillator.

Allowable Subject Matter

6. Claims 1-12, 16, and 20-23 allowed.

7. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 15 was erroneously listed as being allowed in the Examiner's Answer.

8. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 1-2, 5, 6, 10-12 and 23, the prior art of record fails to teach or suggest a portable non-implantable atrial defibrillator with a pair of defibrillator pads and a shock generator operable to shock the patient in response to a shock command all in combination with an analyzer operable to determine from a received cardiac signal whether the patient is experiencing atrial fibrillation, and to enable the shock generator if the patient is experiencing atrial fibrillation. Druz fails to show an analyzer operable to determine from a received signal whether the patient is experiencing atrial fibrillation and to enable the shock generator. Atrial fibrillation is determined by the doctor who is using the defibrillator with ECG display.

With respect to claim 15, the prior art of record fails to teach of suggest a method comprising determining from a cardiac signal whether the patient is experiencing atrial fibrillation by measuring the lengths of R-R intervals, calculating the differences between lengths of contiguous ones of R-R intervals, comparing the differences to a threshold and determining the patient is not experiencing atrial fibrillation if one of the calculated differences is less that the threshold, receiving a shock command from an operator and shocking the patient with a portable shock generator in response to the shock command if the patient is experiencing

atrial fibrillation. In the method of Druz, the determination of whether a patient is experiencing atrial fibrillation is made by the doctor who is using the defibrillator with ECG display.

Regarding claim 17, the prior art of record fails to teach of suggest a method comprising determining from a cardiac signal whether the patient is experiencing atrial fibrillation by determining the patient's heart rate and determining that the patient is not in atrial fibrillation if the heart rate is outside a predetermined range and shocking the patient with a portable shock generator if the patient is experiencing atrial fibrillation. In the method of Druz, the determination of whether a patient is experiencing atrial fibrillation is made by the doctor who is using the defibrillator with ECG display.

With respect to claims 20-22, the prior art of record fails to teach of suggest a method comprising determining from a cardiac signal whether the patient is experiencing atrial fibrillation identifying an operator of a shock generator, and enabling the shock generator if the operator is authorized to operate the shock generator and shocking the patient with the shock generator in response to a shock command if the patient is experiencing atrial fibrillation. In the method of Druz, there is no type of "lock-out" feature for discerning authorized users of the defibrillator.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kristen Droesch

kld

Angela D. Sykes

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700